

## INJECTABLE INTRAOCULAR LENS

### BACKGROUND OF THE INVENTION

The present invention relates an intraocular lens and to materials useful in making intraocular lenses (IOLs), specifically, injectable IOLs, and methods for their preparation. More particularly, this invention relates to high specific gravity silicone materials suitable for making accommodative IOLs which can be injected with greater convenience than current materials.

The human eye is a highly evolved and complex sensory organ. It is composed of a cornea, or clear outer tissue which refracts light rays enroute to the pupil, an iris which controls the size of the pupil thus regulating the amount of light entering the eye, and a lens which focuses the incoming light through the vitreous fluid to the retina. The retina converts the incoming light into electrical energy that is transmitted through the brain stem to the occipital cortex resulting in a visual image. In the perfect eye the light path from the cornea, through the lens and vitreous fluid to the retina is unobstructed. Any obstruction or loss in clarity within these structures causes scattering or absorption of light rays resulting in diminished visual acuity. For example, the cornea can become damaged resulting in edema, scarring or abrasions, the lens is susceptible to oxidative damage, trauma and infection, and the vitreous can become cloudy due to hemorrhage or inflammation.

As the body ages, the effects of oxidative damage caused by environmental exposure and endogenous free radical production accumulate resulting in a loss of lens flexibility and denatured proteins that slowly coagulate reducing lens transparency. The natural flexibility of the lens is essential for focusing light onto the retina by a process referred to as accommodation. Accommodation allows the eye to automatically adjust the field of vision for objects at different distances. A common condition known as presbyopia results when the cumulative effects of oxidative damage diminish this flexibility reducing near vision acuity. Presbyopia usually begins to occur in adults during their mid-forties; mild forms are treated with glasses or contact lenses.

Lenticular cataracts is a lens disorder resulting from protein coagulation and calcification. There are four common types of cataracts: senile cataracts associated with aging and oxidative stress, traumatic cataracts which develop after a foreign body enters the lens capsule or following intense exposure to ionizing radiation or infrared rays, complicated cataracts which are secondary to diseases such as diabetes mellitus or eye disorders such as detached retinas, glaucoma and retinitis pigmentosa, and toxic cataracts resulting from medicinal or chemical toxicity. Regardless of the cause, the disease results in impaired vision and may lead to blindness.

Treatment of severe lens disease requires the lens' surgical removal or pharmacemulsion followed by irrigation and aspiration. However, without a lens the eye is unable to focus the incoming light on the retina. Consequently, artificial lenses must be used to restore vision. Three types of prosthetic lenses are available: cataract glasses, external contact lenses and IOLs. Cataract glasses have thick lenses, are uncomfortably heavy and cause vision artifacts such as central image magnification and side vision distortion. Contact lenses resolve many of the problems associated with glasses, but require frequent cleaning, are difficult to handle (especially for elderly patients with symptoms of arthritis), and are not suited for persons who have restricted tear production. Intraocular lenses are used in the majority of

cases to overcome the aforementioned difficulties associated with cataract glasses and contact lenses.

There are four primary IOL categories: non-deformable, foldable, expansible hydrogels and injectable. Early non-deformable IOL implants were ridged structures composed of acrylates and methacrylates requiring a large incision in the capsular sac and were not accommodative. This large incision resulted in protracted recovery times and considerable discomfort for the patient. In an effort to reduce recovery time and patient discomfort numerous small incision technique and lenses have been developed.

Early lenses designed for small incision implantation were elastomeric compositions that could be rolled or folded, inserted into the capsular sac then unfolded once inside. Occasionally, the fold of the lens before insertion resulted in permanent deformation adversely affecting the implant's optical qualities. Foldable lenses overcame the need for the large incision non-deformable lenses required, but were not accommodative. Moreover, both non-deformable and foldable IOLs are susceptible to mechanical dislocation resulting in damage to the corneal endothelium.

Another approach to small incision IOL implantation uses an elastomeric polymer that becomes pliable when heated to body temperature or slightly above. Once pliable, the lens is deformed along a least one axis reducing its size sufficient for easy insertion through a small incision. The lens is then cooled to retain the modified shape until re-heated. The cooled lens is inserted into the capsular sac and the natural body temperature warms the lens and it returns to its original shape. The primary drawback to the thermoplastic lens is the limited number of polymers that meet the exacting needs of this approach. Most polymers are composed of polymethylacrylate which have solid-liquid transition temperatures above 100° C. Modifications of the polymer substrate requires the use of plastisizers that may eventually leach into the eye.

Dehydrated hydrogels have also been used with small incisions techniques. Hydrogel lenses are dehydrated before insertion and naturally rehydrated once inside the capsular sac. However, once fully rehydrated the polymer structure is notoriously weak due to the large amount of water absorbed. The typical dehydrated hydrogel's diameter will expand from 3 mm to 6 mm resulting in a lens that is 85% water. At this water concentration the refractive index drops to approximately 1.36 which is unacceptable for an IOL. To achieve a refractive index between 1.405 to 1.410 a significantly thicker lens is required; this is even further exacerbated when lens diameters exceed 6 mm.

Recent technological advances have led to the development of injectable IOLs. This lens category is injected directly into the empty capsular sac and cured in situ. Unlike conventional IOLs that are fabricated and shaped before implantation, injectable IOLs are formed inside the eye itself. Once cured, the IOL assumes the shape and exact dimensions of the natural lens. A further advantage to injectable IOLs is that an incision as small as 1.5 mm can be used to remove the natural lens and inject the IOL.

The only silicone material currently used for injectable IOLs is polydimethylsiloxane (PDMS). This silicon material has a refractive index similar to the natural lens and has been used successfully with foldable silicone implants. However, it has been reported that injectable lenses fabricated from PDMS exhibit undesirable qualities associated with its specific gravity. Current PDMS compounds have a specific gravity less than 1.0 and float on the aqueous layer when